

IN THE SPECIFICATION

1. Please replace the paragraph beginning on page 4, line 17 with the following

rewritten paragraph:

b  
-- Testosterone circulates in the blood 98% bound to protein. In men, approximately 40% of the binding is to the high-affinity sex hormone binding globulin ("SHBG"). The remaining 60% is bound weakly to albumin. Thus, a number of measurements for testosterone are available from clinical laboratories. The term "free" testosterone as used herein refers to the fraction of testosterone in the blood that is not bound to protein. The term "total testosterone" or "testosterone" as used herein means the free testosterone plus protein-bound testosterone. The term "bioavailable testosterone" as used herein refers to the non-SHBG bound testosterone and includes testosterone weakly bound to albumin.--

2. Please replace the paragraph beginning on page 14, line 13, with the following

rewritten paragraph:

B<sup>2</sup>  
-- Toxicity and therapeutic efficacy of the active ingredients can be determined by standard pharmaceutical procedures, e.g., for determining LD<sub>50</sub> (the dose lethal to 50% of the population) and the ED<sub>50</sub> (the dose therapeutically effective in 50% of the population). The dose ratio between toxic and therapeutic effects is the therapeutic index and it can be expressed as the ratio LD<sub>50</sub>/ED<sub>50</sub>. Compounds which exhibit large therapeutic indices are preferred. While compounds that exhibit toxic side effects may be used, care should be taken to design a delivery system that targets such compounds to the site of affected tissue in order to minimize potential damage to uninfected cells and, thereby, reduce side effects.--

3. Please replace the paragraph beginning on page 41, line 11, with the following rewritten paragraph:

B3 -- Patients receiving AndroGel® or the testosterone patch achieve "hormonal steady state" only after long-term treatment. Specifically, data involving FSH and LH show that these hormones do not achieve steady-state until many weeks after treatment. Because testosterone concentrations are negatively inhibited by FSH and LH, testosterone levels do not achieve true steady state until these other hormones also achieve steady state. However, because these hormones regulate only endogenous testosterone (which is small to begin with in hypogonadal men) in an intact feedback mechanism (which may not be present depending on the cause of hypogonadism), the level of FSH and/or LH may have little effect on the actual testosterone levels achieved. The net result is that the patients do not achieve a "hormonal steady state" for testosterone even though the  $C_{avg}$ ,  $C_{min}$ , and  $C_{max}$  for testosterone remains relatively constant after a few days of treatment.--

#### IN THE CLAIMS

##### *I. Cancellation of Claims*

Please cancel claims 1-32, 37-40, 43, 44, 46, 47, 51-56, 60, 61, 63, 65-74, 84-87, 94-96, and 100, without prejudice.

##### *II. Substitution of Claims*

Please substitute pending claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99, with the corresponding amended claims, as shown below:

B4 33. (Amended) The method of claim ~~101~~, wherein the subject is eugonadal.